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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,700	04/07/2006	Johannes Bonenberger	DEBE:056US	2064

32425 7590 09/20/2007
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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,700	BONENBERGER ET AL.	
	Examiner	Art Unit	
	Narayan K. Bhat	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-17 are pending in this application.

2. Applicant's election without traverse of invention of group I in the reply filed on July 5, 2007 is acknowledged.

3. Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of group II there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 5, 2007.

4. Claims 1-10, 12-17 are under prosecution.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, 7-10, 12 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Obremski et al (USPGPUB. No. US2002/0001853 published January 3, 2002, herein after Obremski).

Regarding claim 1, Obremski teaches a method for detecting analytes that includes incubating a sample with analyte binding partners (paragraph 0010) able to capture up to 10 billion molecules of the analytes (paragraph 0016, step 'a' of the instant claim), that is at least 2 molecules of the analyte to be detected in the sample are coupled and further teaches that binding partners includes oligonucleotide probes, antibodies and receptor molecules, which are macromolecules of the instant claim.

Obremski also teaches binding partners, i.e., macromolecules are attached to the substrate, i.e., a solid carrier, and by inherency analytes that are incubated with binding partners are coupled to solid carrier to form an analyte capture complex (Paragraph 0011, step 'b' of the instant claim).

Obremski further teaches adding a fluorescence dye to stain the macromolecules (paragraph 0013, step 'c' of the instant claim) and detecting the analytes present in the sample by excitation of the fluorescence dye (paragraph, 0014, step 'd' of the instant claim).

Regarding claim 3, Obremski teaches a method for detecting analytes that includes incubating a sample with binding partners, i.e., macromolecules that are tagged with fluorescent label (paragraph 0013) and further teaches that up to 10 billion analyte molecules are captured by the binding partners (paragraph 0016) that is at least

2 molecules of the analyte to be detected in the sample are coupled (step 'a' of the claim).

Obremski also teaches that binding partners, i.e., macromolecules are attached to the substrate, i.e., a solid carrier, and analytes that are incubated with binding partners are coupled to solid carrier to form an analyte capture complex (Paragraph 0011, step 'b' of the instant claim).

Obremski further teaches detecting the analytes present in the sample by excitation of the fluorescence dye (paragraph, 0014, step 'c' of the claim).

Regarding claim 2, Obremaski teaches a method to detect biotin, i.e., analyte in a sample by the binding partner avidin, a macromolecule on the substrate with a fluorescent dye (paragraphs 0061-0066, step 'c') and further teaches removing the non-bound fluorescence dye from the solid carrier (paragraph 0067. step "c'").

Regarding claim 4, Obremaski teaches a method of removing the non-bound macromolecules (paragraph 0068).

Regarding claims 5 and 12, Obremaski teaches that the macromolecules are nucleic acids, peptide nucleic acids, polyamino acids (paragraph 0010)

Regarding claims 7 and 14, Obremaski teaches that the macromolecules are oligonucleotides probe, antibody or receptor molecules (paragraph 0010) that is,

identical if macromolecules are all oligonucleotide or non-identical if macromolecules are antibodies or oligonucleotides probes.

Regarding claims 8 and 15, Obremaski teaches that the analyte is biotin (paragraph 0061), which has a molecular weight of less than 5000 Dalton.

Regarding claims 9 and 16, Obremaski teaches that the fluorescence dye is a fluorophore (paragraphs 0047-0050).

Regarding claims 10 and 17, Obremaski teaches that the solid carrier is permeable to light and the detection method is implemented by means of a transmitted-light method (paragraph 0038).

7. Claims 1, 3, 5-7, 9-10, 12-14 and 16-17 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Shen et al (USPGPUB. No. US2003/0148335 filed October 10, 2001, herein after Shen).

Regarding claim 1, Shen teaches a method for detecting targets in a sample, i.e., analytes in a sample (Fig. 2, element # 36) that includes incubating a sample with a reporter ligand (Fig. 1, element # 33) able to capture pico molar quantities of analytes in the sample (paragraphs 0199 and 0279, step 'a' of the claim) and further teaches that the reporter ligand include the single stranded oligonucleotide ID tags (Fig. 2, element # 30). The reporter ligand coupled to the oligonucleotide ID tag is the macromolecule of

the claim. Since macromolecule captures 2 pico molar quantities of analytes (>10 billion molecules), it is coupled to at least two molecules of the analytes thus meeting the limitation of the claim.

Shen also teaches further incubating the sample with solid carrier to which capture molecules for the analyte to be detected are coupled, namely incubating with a bead with a reporter ligand (Fig. 2, element # 44, paragraph 0199, step 'b' of the claim).

Shen also teaches direct labeling of the single stranded oligonucleotide ID tags with the fluorescence dye- CY3 to stain the macromolecules (paragraph 0121, step 'c' of the claim) and detecting the analytes present in the sample by excitation of the fluorescent dye (Fig. 2, element # 48, paragraph 0121, step 'd' of the claim).

Regarding claim 3, Shen teaches a method for detecting target in a sample i.e., analytes in a sample that includes incubating a sample with a reporter ligand coupled to the single stranded oligonucleotide with ID tags and further teaches that single stranded oligonucleotide ID tags are directly labeled with the fluorescence dye- CY3 (paragraph 0121). The reporter ligand coupled to the single stranded oligonucleotide ID tag is the macromolecule of the claim. Shen also teaches macromolecules captures pico molar quantities of analytes (paragraphs 0199 and 0279). Since macromolecule captures 2 pico molar quantities of analytes (>10 billion molecules), it is coupled to at least two molecules of the analytes. (Step 'a' of the claim)

Shen further teaches incubating the sample with a solid carrier to which capture molecules of the analyte to be detected are coupled, namely incubating with a bead with

a reporter ligand (Fig. 2, element # 44, paragraph 0199, step 'b' of the claim) and also teaches detecting the analytes present in the sample by excitation of the fluorescent dye (Fig. 2, element # 48, paragraph –0121, step 'c' of the claim).

Regarding claims 5 and 12, Shen teaches that the reporter ligand coupled to the oligonucleotide ID tags, i.e., macromolecules are nucleic acids and polyamino acids (Fig. 2, element # 33, paragraphs 0016, 0018-20).

Regarding claims 6 and 13, Shen teaches that the reporter ligand coupled to the oligonucleotide ID tags, i.e., macromolecules include oligonucleotide ID tag, which is a single stranded oligonucleotide of less than 50 nucleotide in length (paragraphs 0018 – 0020, and 0110), which is in the range of 40 to 80 nucleotides.

Regarding claims 7 and 14, Shen teaches that the reporter ligand coupled to the oligonucleotide ID tags, i.e., macromolecules are nucleic acids and poly amonoacids (Fig. 2, element # 33, paragraphs 0016, 0018-20), which are identical or non-identical.

Regarding claims 9 and 16, Shen teaches an embodiment wherein the fluorescence dye is a phenanthrenes and SYBR dyes or fluorophores (paragraphs 0168-0169).

Regarding claims 10 and 17, Shen teaches that the solid carrier is a bead permeable to light and the detection method is implemented by means of a transmitted-light method (paragraph 0132).

Conclusion

8. No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

Narayan K. Bhat, Ph. D.

Examiner

Art Unit 1634